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August 5, 2003

BY FACSIMILE (214) 821-3834 AND FEDERAL EXPRESS

James C. Barber, Esq.
Law Offices of James C. Barber
4310 Gaston Avenue
Dallas, Texas 75246

Re: Madden, et al. v. Wyeth, et al., Civil Docket 3:03-cv-00167

Subpoena Duces Tecum to the Custodian of Records for Dr. Allen A. Mitchell
Subpoena Duces Tecum to the Custodian of Records for Slone Epidemiology Center

Dear Mr. Barber:

I represent Boston University in connection with the subpoenas served by the plaintiffs in the above-captioned case on the Custodian of Records for Dr. Allen Mitchell and the Slone Epidemiology Center ("SEC") on or about July 23, 2003, with a production date of August 6, 2003. I am writing pursuant to Rule 45(c)(2)(B) of the Federal Rules of Civil Procedure to inform you of Boston University's objection to producing the records requested in Exhibit A of these subpoenas.

The plaintiffs seek production of twenty-five different categories of documents relating to the Boston University Fever Study ("Fever Study"), which was conducted by SEC in 1991-1993. As you know, the Fever Study was sponsored by McNeil Consumer Healthcare ("McNeil") in connection with its application for FDA approval to make Children's Motrin available over-the-counter. The lawsuit pursuant to which you have issued these subpoenas involves a case against Wyeth, which I understand to be a competitor of McNeil. SEC did not undertake the Fever Study on behalf on Wyeth, nor did it have any involvement in Wyeth's request for or receipt of FDA approval to market non-prescription pediatric ibuprofen.

The research, findings, and conclusions of the Fever Study are already in the public domain either through prior submissions to the FDA in connection with McNeil's new drug application or as set forth in a number of peer reviewed articles published by the Fever Study's investigators. The additional data and information sought by the plaintiffs' subpoenas are unreasonable and irrelevant to their litigation against Wyeth.

More specifically, Boston University's objections to plaintiffs' inspection and copying of the materials set forth in Exhibit A of both subpoenas include, but are not limited to, the following:

1. The subpoenas are unreasonable and oppressive in that they impose undue burden and significant expense on Boston University and SEC, neither of which is a party to the underlying litigation and neither of which has any relationship with the plaintiffs or defendants in the underlying case. The requests for "all clinical trials data" and "the entire clinical trial database," as well as "all data" relating to adverse events (see request nos. 1, 2, 3, 5, 21, 24) would alone require production of data on 84,000 individual research subjects, resulting in truckloads of documents. Boston University should not be required to undertake the expense and burden of producing this information when plaintiffs have made no showing that any of this information is relevant to their case against Wyeth, a company that neither sponsored the Fever Study nor received any data from SEC in connection with the Fever Study.

2. The subpoenas seek documents and data that are irrelevant and unnecessary to the plaintiffs' case, in that such documents relate to Children's Motrin, a drug manufactured by McNeil, which is not at issue in the underlying litigation. See request nos. 1, 16, 22. Nothing in the documents held by the SEC has any bearing on the harms allegedly suffered by the plaintiffs from taking a drug manufactured by Wyeth.

3. The subpoenas contravene Rule 45(c)(3)(B) in that they seek disclosure of documents and communications, including e-mails and unpublished reports that represent an unretained expert's opinion or that contain information not describing particular events or occurrences in dispute and that result from an expert's study made not at the request of any party. See, for example, request nos. 18, 23. Neither Dr. Mitchell nor SEC is a party to this lawsuit or an expert witness therein. Plaintiffs appear to be seeking Dr. Lesko's and Dr. Mitchell's raw research data in order to have another expert examine it either to verify the accuracy of findings reported by Drs. Lesko and Mitchell or to be able to conduct other analyses using such data. This is precisely the type of discovery prohibited by Rule 45(c)(3)(B).

4. The subpoenas seek production of raw data in the form of study participants' hospital records, lab results, enrollment forms, questionnaires, and interview forms. See request nos. 14, 15. Provision of such data to the plaintiffs would result in breach of specific confidentiality provisions promised by the investigators to all study participants as part of the enrollment/consent form. Given the volume of raw data at issue (approximately 84,000 study participants), redacting patient information or patient identifiers from questionnaires, interview forms, and hospital records is costly, burdensome, and simply not viable. Further, compelled disclosure could prevent any potential future volunteer subjects from participating in such research studies or other similar research projects if litigation-related discovery requests from third parties could result in a confidentiality breach.

5. The subpoenas seek production of confidential contracts, communications, and business dealings between Drs. Mitchell and Lesko, the SEC, and McNeil, including copies of private contracts between SEC and McNeil to which Wyeth was not a party. See request

nos. 10, 18, 19, 20. Plaintiffs can make no showing that the business relationship between Slone and McNeil has any relevance to this lawsuit against Wyeth, and have no reasonable basis for seeking such documents other than to harass Dr. Mitchell and the SEC or to obtain confidential research, development or commercial information in violation of Rule 45(c)(3)(B).

6. The subpoenas require production of data and documents from SEC which were provided to the FDA and which are readily available through a public records request to the FDA. See request nos. 4, 16. Plaintiffs have made no showing that they are unable to obtain all relevant data from the FDA.

7. The subpoena requests manuscripts of studies performed by SEC. See, for example, request no. 8. The plaintiffs have readily available access to the published articles resulting from the Fever Study and to the referenced works therein. There is no need to require the researchers themselves to provide such materials.

8. The subpoenas seek disclosure of the names and addresses of the approximately 1700 physicians who participated in the Fever Study. See request no. 17. Providing such information will certainly chill physicians' future cooperation in research studies if, as a consequence of participation, the physicians are contacted by plaintiffs seeking to verify information obtained from researchers about them. Such physicians might also knowingly or unknowingly provide information that would allow plaintiffs to identify particular patients.

Please be advised that by listing these objections we are not waiving any other defenses or objections to these subpoenas that we may choose to make in response to this or any further requests by the plaintiffs.

I will be out of my office and essentially unreachable from August 8, 2003, until August 25, 2003, but I am available after that date to discuss this matter further with you, and specifically to see if there is any basis for narrowing disagreement on the issues. If there are any urgent matters relating to these subpoenas while I am away, you may contact my colleague Larry Elswit at (617) 353-2326.

Sincerely,

Erika Geetter

Erika Geetter

cc: Allen A. Mitchell, M.D.
Samuel M. Lesko, M.D.